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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,776	07/10/2003	Craig Heacock	CP241	1994

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,776	HEACOCK ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-86 and 133-145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-86 and 133-145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Receipt is acknowledged of Applicant's letter filed on 30 March 2005, second supplemental preliminary amendment filed on 16 December 2005 and Information Disclosure Statements filed on 18 July 2005 and 16 December 2005.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 49-86 and 133-145, drawn to modafinil in particle form, classified in class 424, subclass 489.

II. Claims 115-132, drawn to a process of making modafinil in particle form, classified in class 424, subclass 489.

The inventions are distinct, each from the other because:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different products, such as particulate formulations of pharmaceuticals other than modafinil.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: a) tablet and b) capsule.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 49 and 115 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: a) narcolepsy, idiopathic hypersomnia, sleep apnea, and obstructive sleep apnea, b) depression, c) Parkinson's disease,

d) urinary incontinence, e) multiple sclerosis fatigue, f) ADHD and g) Alzheimer's disease.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 49 and 115 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. S. Maurice Valla on 13 January 2006, a provisional election was made without traverse to prosecute the invention of Group I, claims 49-86 and 133-145, in tablet form, to treat narcolepsy, idiopathic hypersomnia, sleep apnea, and obstructive sleep apnea. Affirmation of this election must be made by applicant in replying to this Office action. Claims 115-132 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49-86 and 133-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow, et. al. (US 5,618,845).

Grebow, et. al. disclose a pharmaceutical composition comprising modafinil in particle form (col. 2, lines 6-8). The pharmaceutical composition may be used as a method of altering a somnolent state, such as narcolepsy, idiopathic hypersomnia, and other sleep disorders (col. 3, lines 56-58). The method involves administration to mammals of modafinil in particle form of a defined size (col. 3, lines 59-62). The reference indicates that an effective amount of the disclosed pharmaceutical composition is useful for enhancing

alertness, or increasing regularity of sleep rhythms (col. 3, line 67 – col. 4, lines 1-3).

Grebow, et. al. employed several options to analyze modafinil particle size, i.e. laser diffraction particle size analysis, mechanical sieving, optical microscopy, ultracentrifugation, sedimentation, air permeability, electron microscopy, scanning electron microscopy and Coulter Counter techniques (col. 7, lines 33-38).

Grebow, et. al. teach that the size of the modafinil particles is important to the potency and safety profile of the drug (col. 2, lines 8-10). They (Grebow, et. al.) found at least two significant and unexpected advantages when administering modafinil in the form of particles of a defined size (col. 5, lines 21-23). First, they found increased potency of the drug; i.e. smaller average particle size allowed achievement of a set modafinil plasma concentration at a lower dose of the drug (col. 5, lines 23-25). Second, they explain that the safety profile of modafinil can be more accurately controlled because dosing with defined particle sizes proved to be reliable in achieving the desired plasma concentration of drug (col. 5, lines 25-31).

The Grebow, et. al. reference differs from the instant case only in that it does not specifically recognize about 10% of the total cumulative modafinil particles to by smaller than 25μm and about 5% of the total cumulative modafinil particles to be larger than 200μm. However, the particle sizes, including a particular combination, could be determined by one of ordinary skill in the art at the time of the invention, given the teachings in Grebow, et. al., i.e. a

pharmaceutical composition of modafinil comprising distinct particle sizes, and the beneficial effects of such composition (see *supra*). Thus, there is no unexpected result in the two particle size combination of the instant case. The Grebow, et. al. reference uses the same drug as the instant case, to treat patients suffering from the same disease as the instant case, administered in the same way as the instant case, to give the same effect as the instant case.

Absent a showing of an unexpected result by the combination of particle sizes claimed in the instant case, it would be obvious to one of ordinary skill in the art to use the claimed particle size combination of modafinil. The expected result would be treatment of narcolepsy, idiopathic hypersomnia, sleep apnea, and obstructive sleep apnea by enhancing alertness, or increasing regularity of sleep rhythms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NEIL S. LEVY
PRIMARY EXAMINER